# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/717,897 | 11/21/2003 | Jonathan Phillips | 044463-0264 | 9078 |

22428 7590 10/03/2006

FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

| EXAMINER | |
|---|---|
| COLLINS, CYNTHIA E | |
| **ART UNIT** | **PAPER NUMBER** |
| 1638 | |

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/717,897 | PHILLIPS ET AL. | |
| | Examiner | Art Unit | |
| | Cynthia Collins | 1638 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 2-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 2-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09052006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The Amendment filed July 14, 2006 has been entered.

Claims 1 and 7-20 are cancelled.

Claims 2-6 are currently amended.

Claims 2-6 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

### *Claim Rejections - 35 USC § 112*

Claims 2-6 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed April 14, 2006.

Applicant's arguments filed July 14, 2006 have been fully considered but they are not persuasive.

Applicants maintain that in the current application, the disclosure is sufficient to meet the written description requirement in line with the reasoning provided by the Federal Circuit. Applicants point out that claim 2 has been amended to recite a composition comprising SEQ ID No: 47 and functional variants, and that, in addition, claim 3 has been amended to recite functional variants that are at least 90% identical to SEQ ID No: 47. Applicants also point out

that the sequence for SEQ ID No: 47 is provided in the application, as are Examples incorporating this sequence. Applicants maintain that descriptions of functional variants are found throughout the application, for example, on pages 43-44. Applicants additionally point out that methods for making and using nucleic acids, such as the functional variants, complements, or reverse sequences, are well known to one of skill in the art and are described in the application, for example, on pages 44-46 and in the Examples. Applicants maintain that a person of skill in the art could readily identify if a sequence is 90% identical to the provided SEQ ID No: 47. Applicants further point out that the application provides extensive disclosure about the technology and background of vascular preferred promoters and methods of analyzing sequences, and Applicants maintain that these disclosures would satisfy a person of skill in the art that the technology is adequately described in the application. Applicants also point out that examples for each and every sequence claimed are not required by the Federal Circuit, and that there is no rule that every sequence must be provided in the application when a person of skill in the art could readily identify the invention claimed. (reply pages 5-6)

The rejection is maintained because the disclosure of the single polynucleotide of SEQ ID NO:47 that functions to confer vascular and xylem preferred polynucleotide transcription does not adequately describe the claimed genus of polynucleotide sequences which encompasses numerous undisclosed and uncharacterized functional variants of SEQ ID NO:47, including functional variants of SEQ ID NO:47 that have greater than or equal to 90% sequence identity to SEQ ID NO:47, and including polynucleotides that are complementary to the sequences in claim 2 or that are that are reverse complements to the sequences in claim 2. Further, the outstanding rejection imposed no requirement for examples for each and every sequence; the outstanding

rejection merely stated that a representative number of species falling within the scope of the claimed genus had not been described. Regarding the descriptions of functional variants on pages 43-44, the Examiner maintains that while the term functional variant is defined at pages 43-44, pages 43-44 do not describe the structure of any actual functional variant of SEQ ID NO:47.

With respect to Applicant's assertion that methods for making and using nucleic acids, such as the functional variants, complements, or reverse sequences, are well known to one of skill in the art and that this technology is adequately described in the application, the Examiner maintains that the outstanding rejection was not predicated on a failure to describe such technology; the outstanding rejection was predicated on a failure to describe the claimed sequences. In this regard it is also noted that whether a nucleic acid sequence is described is not dependent on whether the specification provides an enabling disclosure. See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), which discusses the description of a claimed human cDNA sequence based on the disclosure of a rat cDNA sequence and a method for obtaining the human cDNA sequence:

> The patent describes a method of obtaining this cDNA by means of a constructive example, Example 6. This example, however, provides only a general method for obtaining the human cDNA (it incorporates by reference the method used to obtain the rat cDNA) along with the amino acid sequences of human insulin A and B chains. Whether or not it provides an enabling disclosure, it does not provide a written description of the cDNA encoding human insulin, which is necessary to provide a written description of the subject matter of claim 5. The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. (*Lilly*, 43 USPQ2d at 1405)

In the instant case, while the specification provides a process for obtaining functional variants of SEQ ID NO:47, there is no further information in the specification pertaining to the relevant structural or physical characteristics of these functional variants; in other words, it thus does not describe variants of SEQ ID NO:47 that that function to confer vascular and xylem preferred polynucleotide transcription. Further, describing methods for preparing functional variants of SEQ ID NO:47 does not necessarily describe the nucleic acid sequences of the variants prepared.

Claims 2-6 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule of SEQ ID NO: 47, does not reasonably provide enablement for other isolated nucleic acid molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed April 14, 2006.

Applicant's arguments filed July 14, 2006 have been fully considered but they are not persuasive.

Applicants note that claims 2-6 are amended to recite compositions of SEQ ID No: 47 and related sequences. Applicants maintain that the Examples provide the necessary steps for enabling the use of SEQ ID NO: 47, and also the enabling disclosure for other sequences described in the application. Applicants point out that the specification provides data for over 50 sequences in Examples 1-9. Applicants maintain that these results indicate that the use of the claimed sequences was sufficiently described and the steps are able to predictably provide information regarding the sequences. Applicants maintain that a person of skill in the art reading

the specification can readily identify the sequences described in the claims and make the sequences using techniques provided in the specification or known to one of skill in the art, and that the sequences can then be tested using the procedures outlined in the specification and enabling for over 50 different sequences described in the application. Applicants maintain that these findings indicate the enablement of the claimed invention. (reply page 7)

The full scope of the claimed invention is not enabled because it is unpredictable whether variants of SEQ ID NO:47 would function to confer gene expression in a plant cell, and whether SEQ ID NO:47 or variants thereof would be capable of downregulating the expression of an operably linked gene, because a promoter requires the presence of specific nucleotides and nucleotide sequence motifs in a polynucleotide in order to exhibit specific functional attributes, which nucleotides and motifs may not be present in variants of SEQ ID NO:47. In the instant case Applicant has not provided sufficient guidance with respect to the identity and location of key nucleotides and regulatory regions required for basal or tissue-specific promoter function, or for downregulating the expression of an operably linked gene, in variants of SEQ ID NO:47. Absent such guidance it would require undue experimentation for one skilled in the art to use variants of SEQ ID NO:47. The data provided for over 50 sequences in Examples 1-9 do not provide such guidance, because these sequences do not met the structural requirements of the rejected claims, and therefore fall outside of the scope of the claimed invention.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2, and claims 3-6 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 is indefinite in its dependence from claim 1, which is cancelled.

### *Claim Rejections - 35 USC § 102*

Claim 4 remains rejected under 35 U.S.C. 102(b) as being anticipated by Polvere R.I. et al. (GenBank Accession No. U88240, *Trichinella spiralis* hypothetical ORF 2.20 mRNA, partial cds, March 4, 1997), for the reasons of record set forth in the office action mailed April 14, 2006.

Applicant's arguments filed July 14, 2006 have been fully considered but they are not persuasive.

Applicant maintains that the amendment of claim 4 obviates the rejection (reply page 7).

The Examiner maintains that the amendment of claim 4 does not obviate the rejection because Polvere R.I. et al. teach a sequence comprising at least 20 contiguous bases of SEQ ID NO:47. The sequence of Polvere R.I. et al. is therefore inherently complementary within this region to SEQ ID NO:47.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Remarks***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cynthia Collins
Primary Examiner
Art Unit 1638

CC

Cynthia Collins
9/25/06